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October 1, 2013

VIA E-FILING AND HAND DELIVERY

The Honorable Richard G. Andrews
United States District Court
844 N. King Street, Room 2325
Wilmington, DE 19801

CONFIDENTIAL - FILED UNDER SEAL

Re: *Novartis Pharmaceuticals Corp., et al. v. Alvogen Group, Inc., et al.*,
C.A. No. 1:13-cv-00052-RGA

Dear Judge Andrews:

This firm, together with Axinn, Veltrop & Harkrider LLP ("Axinn"), represents defendants Alvogen Pine Brook Inc. and Alvogen Group, Inc. (collectively "Alvogen"), as well as non-party [redacted], in the above-captioned action. We write in response to Plaintiffs' September 30, 2013 letter. (D.I. 56.)

I. BACKGROUND

Plaintiffs have had Alvogen's ANDA in hand since March 26, 2013 and thus know full well that Alvogen's ANDA Product does not contain an antioxidant. Faced with this obstacle to their infringement claim, Plaintiffs have embarked on a full-scale fishing expedition, the first step of which is to demand the production of extraordinary quantities of not only the ANDA Product but also of components of the ANDA Product and intermediaries used to manufacture those components. As Plaintiffs know and have acknowledged, however, Alvogen did not develop and does not manufacture the ANDA Product. (Ex. 1, May 10, 2013 Letter from D. Silver to Hon. R. Andrews.) Instead, all dosage strengths of the ANDA Product were developed and will be manufactured by [redacted]. (Id.) Plaintiffs therefore seek production through a subpoena directed at [redacted]. (D.I. 56, Ex. 2.)

[redacted] is a small [redacted] manufacturing company and not a party in this case. Plaintiffs disingenuously suggest that [redacted] has somehow acquiesced to be treated as a party. (D.I. 56 at 3 n.2.) Although [redacted] offered to waive the requirement that Novartis go through the Hague Convention to serve its subpoena, it has never consented to being treated as a party. (See Rule 16 Conf. Tr. at 5:5-6:8; 13:5-14, March 6, 2013, D.I. 25.) It is unfortunate that Plaintiffs persist in their mischaracterization of [redacted] status despite requests that they cease doing so. (Ex. 2, July 9, 2013 Letter from J. Liu to C. Loh.) Contrary to Plaintiffs' insinuations, [redacted] has worked in good faith to cooperate with Plaintiffs' subpoena requests. Thus, it has already produced some materials and agreed to produce reasonable and non-disruptive quantities of other materials. (Ex. 3, Sept. 19, 2013 Letter from C. Landmon to C. Loh.)

II. PLAINTIFFS' PRODUCTION REQUESTS

Plaintiffs compile their production requests in a table set out in the [Proposed] Sealed Order attached to their Sept. 30 letter ("Proposed Order"). Plaintiffs' requests can be categorized

in four groups of items: (1) items [redacted] has already agreed to produce; (2) items [redacted] has informed Plaintiffs that it does not possess; (3) items [redacted] has offered to produce in reasonable quantities but that Plaintiffs are demanding, without substantive explanation, in excessive quantities; and (4) items that cannot have any relevance to the issue of infringement.

A. [redacted] Has Already Agreed to Produce Two of the Items in the Requested Quantities.

Plaintiffs request that the Court order [redacted] to produce "5 g [redacted]" and "20 g rivastigmine." (Proposed Order at 1.) This is an extraordinary and unnecessary request given that [redacted] has already *agreed* to produce these materials in the requested quantities. (Ex. 3, Sept. 19, 2013 Letter from C. Landmon to C. Loh.)

B. [redacted] Has Informed Plaintiffs that It Does Not Possess Three of the Requested Items.

Plaintiffs request that the Court order [redacted] to produce "500 g [redacted]," "500 g [redacted]" and "200 [redacted]" (Proposed Order at 1-2.) This is again an extraordinary and unnecessary request given that [redacted] counsel explained to Plaintiffs during the September 26 meet-and-confer *that* [redacted] *do not possess these items*. The requested [redacted] items are used in the manufacture of the [redacted] items that Plaintiffs also request. [redacted] does not manufacture the [redacted], however, and does not have the [redacted] items to produce. [redacted]. [redacted] All this has been explained to Plaintiffs, and it is unfathomable why they are asking the Court to order [redacted] to produce items that they know it does not possess [redacted].[1]

C. Plaintiffs Are Requesting Unreasonable and Excessive Quantities of Several Items.

Plaintiffs request that the Court order [redacted] to produce 400 patches from each of the three ANDA-listed batches of the 4.6 mg/24 hr ANDA Product, 200 patches from each of the three ANDA-listed batches of the 9.5 mg/24 hr ANDA Product, and 200 patches from the ANDA-listed batch of the 13.3 mg/24 hr ANDA Product. (Proposed Order at 2.) In other words, Plaintiffs request the production of *2000* samples of Alvogen's ANDA Product.

The number of patches requested by Plaintiffs is out of proportion with what is necessary and customary in ANDA cases. Indeed, Plaintiffs nowhere explain *why* they should need such a quantity of patches. Alvogen and [redacted] have offered to produce 100 patches from each of the ANDA-listed batches for each strength, for a total of 700 patches. This is more than enough for any reasonable amount of testing that Novartis could conduct. It is also, to the best of our

[1] These items are also irrelevant to the issue of infringement because they are not part of the pharmaceutical composition. The [redacted] items are used to manufacture a component of the ANDA Product, [redacted].

knowledge, commensurate with the number of product samples that parties in the other litigations involving the same patents have provided. For example, in Civil Action No. 11-1077-RGA (the "Watson Case"), Plaintiffs' expert discussed tests on only 450 patches.

Plaintiffs further request "500 g [redacted]" and 1 kg of [redacted]. (Proposed Order at 1-2.) These are excessive quantities out of proportion with the quantities required for pharmaceutical testing. Furthermore, and as has been explained to Plaintiffs, the production of these quantities of materials is unduly burdensome because it would disrupt [redacted] ability to manufacture patches for other markets.[2] See Fed. R. Civ. P. 45(c) ("A party . . . serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena."). [redacted] has therefore offered to produce 20 grams of each of these items. This amount is reasonable for pharmaceutical testing and can be produced by [redacted] without undue burden or disruption.[3]

Plaintiffs assert that 20 grams "are insufficient to run the test presently contemplated by Plaintiffs' expert." (D.I. 56, at 3.) Revealingly, however, Plaintiffs never say what quantity *would* be sufficient. All they offer is that Watson produced the requested 1 kg quantities in the Watson Case. (Id.) But Watson is materially differently situated. First, Watson is a *party* in the litigation and thus has different obligations than a non-party such as [redacted]. Second, Watson appears to be a substantially larger company than [redacted]. It is hardly surprising, therefore, that Plaintiffs' request could be accommodated by Watson but is unduly burdensome for [redacted].

D. Plaintiffs Are Requesting Items that Have No Relevance to the Issue of Infringement.

Finally, Plaintiffs request the production of 5 square meters [redacted]. (Proposed Order, at 1.) These items are not part of the pharmaceutical composition but are present merely to provide structure and to protect the sticky adhesive layer of the patch prior to use. As such, they cannot be relevant to the issue of infringement. Plaintiffs have offered no reason for their relevance, referring instead to the Watson Case and asserting in conclusory fashion that they "indisputably established the relevance of the components of the accused ANDA product . . . ." (D.I. at 3 n.3) To the best of our knowledge, however, the only "component" at issue in that case was the adhesive – not the types of items Plaintiffs request here.

For the above reasons, the Court should deny Plaintiffs' Proposed Order.

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[2] Plaintiffs incorrectly state that "Axinn Veltrop . . . had not investigated and could not identify specifically what the undue burden is." (D.I. 56, at 1-2.) On the contrary, counsel explained to Plaintiffs that [redacted] does not store large quantities of these materials and that Plaintiffs' request would consequently disrupt [redacted] manufacturing process.

[3] Plaintiffs state that they are willing to pay for the materials and contend that this should remove the burden. (D.I. 56, at 3.) It does not. To the extent Plaintiffs contend that [redacted] can purchase these materials to produce to Plaintiffs, there is no reason why [redacted] employees should be taken away from their daily duties to act as Plaintiffs' purchasing agent. Nothing prevents Plaintiffs from purchasing these materials directly from the supplier.

Respectfully submitted,

/s/ Dominick T. Gattuso

Dominick Gattuso (#3630)

Enclosures

cc: Counsel of Record (via e-mail)